PRESCRIBING INFORMATION
(Please consult the Summary of Product Characteristics (SmPC) for further information)

Zirtek Allergy Tablets and Oral Solution (cetirizine dihydrochloride)

Active Ingredients: Cetirizine dihydrochloride *Tablets:* 10 mg; *Oral solution:* 1 mg/ml.
Indications: Relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis. Chronic idiopathic urticaria.
Dosage and Administration: *Adults and over 12 years:* 10 mg once daily. *Children aged 6 to 12 years*: 5 mg twice daily. *Children aged 2 to 6 years*: 2.5 mg twice daily; only use oral solution in children 2-6 years of age.
Contraindications: Hypersensitivity to active ingredients or excipients, hydroxyzine, or piperazine derivatives. Severe renal impairment (creatinine clearance <10 ml/min). **Warnings and Precautions:** Caution in epilepsy, where risk of convulsions or urinary retention and with alcohol. Allergy skin tests are inhibited. Rebound pruritus and/or urticaria may occur. *Oral solution:* Methyl-parahydroxybenzoate and propylparahydroxybenzoate may cause allergic reactions (possibly delayed). Patients with fructose intolerance. *Tablets*: galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** Concurrent use of alcohol and CNS depressants may reduce alertness. **Fertility, Pregnancy and Lactation:** Caution with pregnancy or breast-feeding. **Driving etc:** Patients experiencing somnolence should refrain from driving, potentially hazardous activities or operating hazardous machinery.
Adverse Effects: *Uncommon*: agitation, paraesthesia, diarrhoea, pruritus, rash, asthenia, malaise. *Rare*: oedema, hepatic function abnormal, convulsions, aggression, confusion, depression, hallucination, insomnia, hypersensitivity, tachycardia, urticaria, weight increased. *Very rare*: thrombocytopenia, anaphylactic shock, tics, dysgeusia, syncope, tremor, dystonia, dyskinesia, accommodation disorder, blurred vision, oculogyration, angioneurotic oedema, fixed drug eruption, dysuria, enuresis. *Not known*: increased appetite, suicidal ideation, nightmare, amnesia, memory impairment, vertigo, hepatitis, acute generalized exanthematous pustulosis, arthralgia, urinary retention. After discontinuation, pruritus and/or urticaria have been reported.
Legal Category: Medicinal products not subject to medicinal prescription.
Marketing Authorisation Numbers: Tablets: PA 0891/008/005. Oral Solution: PA 0891/008/003. **Further information is available from Marketing Authorisation Holder:** UCB Pharma (Ireland) Ltd, United Drug House, Magna Drive, Citywest Road, Dublin 24, Ireland. Medical Information Direct Line: (+353) 01 463 2371 Email: UCBCares.IE@ucb.com.
Date of Revision: July 2019 (IE-P-IE-ALY-1900063).
Zirtek is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at http://www.hpra.ie/homepage/about-us/report-an-issue for Ireland. Adverse events should also be reported to UCB.